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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/050,359 03/31/98 FOWLKES

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001444 HM22/1205
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EXAMINER

WESSENDORF, T

ART UNIT	PAPER NUMBER
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1627
DATE MAILED:

12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/050,359

Applicant(s)

Fowlkes et al

Examiner

T. Wessendorf

Group Art Unit

1627



☒ Responsive to communication(s) filed on 9/8/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 25-38 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 25-38 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claims 25-31 are pending in the instant application. Claims 1-24 have been canceled.

The specification is objected to because it is not clear whether the instant invention is the invention of a sole inventor since the specification at e.g., page 92 recites e.g., "...to do this I would carry out..." (see also page 105) or several inventors as set forth in the oath or declaration.

Clarification is requested.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant(s) may become aware in the specification.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-38 are rejected under 35 U.S.C. 101 because the invention lacks patentable utility for reasons advanced in the last Office action.

It is argued that the claimed panels of peptide libraries are used to evaluate materials other than themselves. However, as implied, the panel of libraries of peptides per se do not have utility per se. It is further argue that once a peptide that

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binds a target protein is identified ,it is used as a reagent in a screening of a complementary library. But applicants is not claiming the binding peptide but a panel of libraries of no utility. A patent application is a not a hunting license rather, a reward for the successful accomplishments of a search. An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is in fact "useful" in a patent sense. A collection or mixture of different compounds does not have a specifically identified utility, rather an invention whose specific utility requires "intermediate" or "for research purposes" which are not helpful in determining if applicant has identified a specific utility for the claimed invention (i.e., structured panel of library). (See MPEP 2107).

Applicants' arguments as to the pragmatic proof of the practical utility of combinatorial libraries is that such libraries are commercially bought and sold. Applicants rely upon the England Biolabs catalogue to show the commercial availability of a library kit. Applicants are not claiming a kit. Furthermore, all of these kits relate to a particular type of library unlike the instantly claimed undefined, unstructured etc. library. There is nothing of record that the alleged commerciality was not due

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to business events extraneous to the merits of the claimed invention. [See further Lebl et al (Biopolymers) at e.g., page 177, Library techniques to page 178, col. 1.]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A). The as-filed specification does not provide support for the newly presented claims to "the middle 50% of the peptides". The original disclosure recites for said determination with the given peptide sequence, e.g., page 25.

B). The specification does not provide a written description for the claimed structured panel of library and a peptide wherein the constant residue is within the middle 50% of the sequence. The disclosure does not describe how a structured panel can be made from a plurality of libraries, how the

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plurality of library form or structured into a panel or the minimum or maximum limit of the plurality contained in any one of the panel and a constant residue that is within 50% of the sequence. It is noteworthy, applicants' disclosure at e.g., page 28, lines 4-23. Also, applicants' REMARKS at page 6 which recites that the panel of libraries have not been screened and may still be screened separately.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claims 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

B). Claim 31 is indefinite as to the metes and bounds of the structured panel that consists of a plurality of peptide libraries. Furthermore, the term "fixed", within the claimed

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context, is unclear in the absence of any peptide sequence and the arbitrary determination from the ends of the peptide sequence provides for confusion and ambiguity. Furthermore, the term "screenable" fails to ascertain the claimed invention with precision i.e., as to whether said panel has been screened or only capable of being screened. The phraseology "structured panel" is not an art recognized term.

C). Claim 34 recitation of "the overall diversity of the panel", "the diversity of the peptides in a given library at a biased position does not exceed 3" lack antecedent basis of support from the base claim.

D). Claim 35 is confusing where a nucleotide sequence is being claimed or a peptide library. This claim appears to be a duplicate of claim 33.

E). The terms "first" and "second" positions are relative terms and appear to be an arbitrary assignment of said positions. Since no peptide sequence, either by length or kind of amino acid residues are provided, hence, for a given library of peptide sequence said arbitrary assignments provide for confusion and ambiguity.

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F). Claims 28 and 29 recitation of the variables m and n lack support from the base claim 31 which does not recite for said variables, m and n.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 28-29, 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as

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obvious over Pinilla et al for reasons of record or under 102(e) over Pinilla (5,556,762).

It is argued that the presently claimed 31 is in a closed format. However, even with the use of the word 'consisting' of the specific peptide of Pinilla would fall within the broad, unspecified peptide sequence or at least suggests an array with a constant residue at the mid-portion of the peptide sequence. However, see specifically Table 1, page 223 of Pinilla wherein the constant residues at the positional scanning is 05 and 06, wherein the constant residue is at the middle of the peptide sequence. Applicants' arguments that Pinilla's sequence is less than 5 residues is not well taken especially in the absence of any recited peptide sequence. Note the specification which recites that the peptide can be from 2-20 residues. Applicants' arguments that Pinilla does not teach a 2 position constants is also a teaching away from the disclosure e.g., page 28 which recites that "...while screening this number of libraries may be possible, the increase in the number of binding peptides would probably not justify the complexities of the task..." (Emphasis added). Applicants' further arguments as to the structure of the peptide being 01-(X)4-02-(X)5 is not commensurate in scope with the claims which does not recite for any peptide structure.

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Pinilla ('762Patent) basically discloses the same array as Pinilla (Biopolymers, 1995).

Claims 25, 28, 29, 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huffman for reasons advanced in the last Office action.

Applicants argue that Hoffman discloses a biased library at the ends and not middle of the peptide sequence. Attention is directed to page 6, line 28 i.e., the peptide sequence e.g., X1-X2-X3-O4-X5-X6.

Claims 32-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spatola for reasons set forth in the last Office action.

Applicants admit that there is one scanning residue, which scans positions 1-4 and corresponds to the second position of claim 32. But argue that AA5 does not corresponds to the first position of claim 23 since the base claim 21 is not the same in all libraries. Claim 21 is canceled. As will be appreciated by one having ordinary skill in the art, in cyclic peptide, due to the symmetry of the molecule, the positions of all defined and variable amino acid residues are relative.

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Claims 25, 28, 29, 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Holmes for reasons set forth in the last Office action.

Applicants' arguments with respect to claims 21-23 is not unclear since all of these claims are canceled.


No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D., can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


T. Wessendorf
Patent Examiner
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12/1/00